

In re: Morgan et al.  
Application No.: 10/542,115  
Filing Date: July 12, 2005  
For: *PORCINE COLLAGEN FILM*

## REMARKS

Claims 1–21 are currently pending in this application. In response to the present Action, Applicants respectfully request entry of the claim amendments presented herein and further consideration of the present application in view of these amendments and the remarks provided below.

### **Support for Claim Amendments**

The amendments presented herein have been made to recite particular aspects of the invention so as to expedite the prosecution of the present application to allowance in accordance with the USPTO Patent Business Goals (65 Fed. Reg. 54603, September 8, 2000). These amendments do not represent an acquiescence or agreement with any of the outstanding rejections.

Claims 1–20 are amended herein to more particularly point out what Applicants regard as the invention. Support for these amendments can be found in the specification as originally filed. The points raised by the Examiner are addressed hereinbelow in the order in which they are raised in the Action.

### **Claim Objections:**

Claims 11 and 18 are objected to for informalities. Although the Examiner indicates in the Action that Claim 8 is objected to, it appears to Applicants that Claim 18 is the actual claim at issue. In response, Applicants amend Claims 11 and 18 herein accordingly. Applicants believe that the present amendments address the concerns of the Examiner in full. However, should the Examiner have any further issue in this regard, Applicants respectfully solicit the Examiner suggestions as to bring this matter to a resolution.

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**Claim Rejections - 35 U.S.C. § 112:**

Claims 2–6, 8, 9, 12, 16 and 19 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim what Applicants regard as the invention.

Applicants amend Claims 1 and 2–6 herein to provide proper antecedent basis for the recitation, “fat content.” Claim 8 is amended herein to point out that less than 5% by weight refers to collagen derived from sheep, poultry, birds, and/or fish. Claim 9 is amended herein to point out that the ratios of 0:100 to 10:90 refer to the ratio of collagen derived from young pigs to collagen derived from sows. Claim 12 is amended herein to recite “alginate glycol” to provide proper antecedent basis for this recitation. Claim 16 is amended herein to provide proper antecedent basis for the recitation “collagen solids content.” Lastly, Claim 19 is amended herein to point out that the collagen content refers to the collagen content of the film. In view of the foregoing, Applicants believe that the issues raised by the Examiner in this rejection have been addressed. Accordingly, Applicants respectfully request that the instant rejection be withdrawn.

**Claim Rejections - 35 U.S.C. § 102:**

Claims 1–9, 13, 15, and 17–21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,482,240 to Eckmayer et al. (hereinafter, “Eckmayer et al.”). It is the assertion of the Examiner that Eckmayer et al. teach collagen membranes and methods of preparing the same that meet all the limitations of the instantly rejected claims.

Case law holds and the Manual for Patent Examination Procedure (“M.P.E.P.”) states that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). Additionally, anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed

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invention. *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000). Furthermore, a finding of anticipation further requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art. *See Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Additionally, the cited prior art reference must be enabling, thereby placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964). Thus, the prior art reference must adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention.

Eckmayer et al. specifically describe the production of collagen membranes from porcine rinds. The fat content is reduced by an enzyme defatting process, which is slow and expensive. The basis of the present invention is in the discovery that the use of sow collagen results in collagen films, which have superior mechanical properties. In general, as one of skill in the art would appreciate, films and casings from porcine collagen have had insufficient strength for practical use. Eckmayer et al. is silent in regard to the use of sow collagen in the preparation of a collagen film. In view of the foregoing, Applicants submit that the discussions of Eckmayer et al. do not anticipate the instant claims, in that the discussions of Eckmayer et al. do not teach all the limitations of the present claims for which Applicants respectfully request that the instant rejection be withdrawn.

Claims 1, 7-9, 13, 15-18 and 21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,196,223 to Shank (hereinafter, "Shank"). It is the assertion of the Examiner that Shank discloses a method of preparing sausage casings from pig skins that meet all the limitations of that which is claimed.

Shank refers to using "pig skins" in preparing sausage casings and is silent as to whether they are derived from young pigs or sows. There is no attempt to control the fat content and the casings produced by the method described by Shank have poor mechanical properties. As set forth on page 2 of the present specification, the casings produced by the method of Shank do not have adequate strength for use in commercial stuffing equipment. As with the discussions in

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Eckmayer et al., the discussions of Shank are silent in regard to the use of sow collagen in the preparation of a collagen film. In view of the foregoing, Applicants submit that the disclosures of Shank do not anticipate the instant claims, in that the discussions of Shank do not teach all the limitations of the present claims for which Applicants respectfully request that the instant rejection be withdrawn.

Claims 1–21 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication No. 2005/0031741 (hereinafter, the '741 Application). It is the assertion of the Examiner that the '741 Application teaches collagen casings or film made from an extrudable collagen gel, wherein the collagen is porcine collagen that meets all the limitations of that which is instantly claimed.

Applicants submit that the '741 Application discusses tubular casings, whereas the present claims are directed to an extruded film. The Examiner has determined the term “film” to be functionally equivalent to the term “casing”, which is discussed in the '741 Application. However, the terms “casing” and “film” are terms of art, which are well known in the industry and have well-established and quite different meanings. It can be appreciated that an extruded casing is tubular, whereas an extruded film is planar. There is no disclosure in the '741 Application of the production of a non-tubular film. Conversely, there is no disclosure in the present application that the film may be converted into a tubular casing. The terms have clear and different meanings, as one of skill in the art would appreciate.

Thus, Applicants present that there is a clear distinction between collagen casings, such as those disclosed in the '741 Application, and the collagen films of the present invention. In view of the foregoing, Applicants assert that the '741 Application does not anticipate the instant claims for which Applicants respectfully request that the instant rejection be withdrawn.

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**Claim Rejections - Double Patenting**

Claims 1–21 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1–33 of the '741 Application.

In response, Applicants submit herewith a terminal disclaimer in compliance with 37 CFR § 1.321 with respect to the '741 Application. Applicants note that the submission of this terminal disclaimer in no way represents an acquiescence to the outstanding rejection or an acknowledgement that the subject matter of the pending claims is obvious over the cited claims of the '741 Application.

Accordingly, Applicants respectfully submit that the filing of this terminal disclaimer would obviate the present rejection, to which Applicants respectfully request its withdrawal.


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### CONCLUSION

Applicants believe that the points and concerns raised by the Examiner in the Action have been addressed in full, it is respectfully submitted that this application is in condition for allowance, which action is earnestly solicited. Should the Examiner have any remaining concerns, it is respectfully requested that the Examiner contact the undersigned Attorney at (919) 854-1400 to expedite the prosecution of this application to allowance.

A Petition and Fee for Extension of Time and a Submission of Terminal Disclaimer are included with this response for a three-month extension of time. Applicants hereby authorize the Commissioner to charge Deposit Account No. 50-0220 in the amount of \$1,150.00 (\$1,020.00 as fee for the extension and \$130.00 for the submission of a terminal disclaimer). Applicants believe this amount to be correct; however, the Commissioner is hereby authorized to charge any deficiency or credit any refund to Deposit Account No. 50-0220.

Respectfully submitted,



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#### CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on July 23, 2007.



Tracy Wallace